

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 10, 2017

Matthew R. Schneider Authorized Representative Garvie Schubert Barer c/o EMD Performance Materials Corporation 1000 Potomac Street NW, Second Floor Washington, DC 2007-3501

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Removing

expiration date and amending the product label to add additional marketing claims and

graphics.

Product Name: Bug Repell IR3535 10% Lotion

EPA Registration Number: 70759-2 Application Date: 03/30/2017 OPP Decision Number: 527830

Dear Mr. Schneider:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims

Page 2 of 2 EPA Reg. No. 70759-2 OPP Decision No. 527830

made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Menyon Adams by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

andrew . Buycelow

Enclosure

### (Front Panel)

## Bug Repell IR3535® 10% Lotion

## KEEP OUT OF REACH OF CHILDREN WARNING

#### **ACTIVE INGREDIENT**

## **FIRST AID** [optional front and back panel] If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.
- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
- For information on this pesticide product call the National Pesticide Information Center at 1-800-858-7378.

EPA Reg. No. 70759-2 EPA Est. No. \_ EMD Performance Materials Corporation One International Plaza Suite 300 Philadelphia, PA 19113 © 2008 EMD Millipore Corp. - ALL RIGHTS RESERVED [optional front and back panel] 128 FL.OZ (3785 ml); 32 FL.OZ (946 ml); 8 FL.OZ (236 ml); 4 FL.OZ (118 ml); 2 FL.OZ (59 ml); 1.7 FL.OZ (50 ml); 0.16 FL.OZ (5 ml); 1.13 FL.OZ (4 ml)

[Batch Code \_ or Lot Number [or similar phrase]

### ACCEPTED

08/10/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 70759-2

(Back Panel)

### **PRECAUTIONARY STATEMENTS**

HAZARDS TO HUMANS- Warning: For external use only. Causes substantial but temporary eye injury. Do not get in eyes. Discontinue use and consult a doctor if irritation or rash occurs.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

# REPELLENCY- REPELS MOSQUITOES AND TICKS FOR UP TO 8 HOURS [optional front and back panel]

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not allow children to handle this product, and do not apply to children's hands. When using on children, apply to your own hands and then put it on the child. After returning indoors, wash your child's treated skin and clothes with soap and water or bathe. FOR CONTINUED PROTECTION: reapply about every 8 hours or sooner if effectiveness is diminished; not to exceed 3 applications per day.

### STORAGE AND DISPOSAL

**Storage:** Store in cool dry place away from heat or flame. Always store insect repellents safely out of the reach of children.

### Disposal:

**If Empty: Nonrefillable Container.** Do not reuse or refill this container. Place in trash or offer for recycling if available.

If Partly Filled: Call your local solid waste agency or call 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

### **Optional Label Claims:**

Use only as directed.

Avoid contact with plastics, costume jewelry, leather and synthetic fibers.

May damage painted or varnished surfaces, including nail polish.

**DEET free** 

**DEET alternative** 

Complete protection against mosquitoes and ticks for up to 8 hours

Effective, dependable protection

Protection [you can count on for up to 8 hours] [from mosquitoes that may carry (transmit) (Zika), (chikungunya), (dengue fever), (West Nile), (malaria), (yellow fever), (and) (encephalitis)]

Repels mosquitoes that may carry (transmit) (Zika) (chikungunya) (dengue fever) (and) West Nile (for up to 8 hours)

Helps to repel mosquitoes and ticks that can transmit vector-borne diseases such as Zika, chikungunya, dengue fever, West Nile, malaria, yellow fever, encephalitis, and Lyme disease

Ticks can transmit Lyme disease

Mosquitoes can transmit diseases like Zika, chikungunya, dengue fever, West Nile, malaria, yellow fever, and encephalitis

Long protection for the whole family

8-hour protection for the entire family

For the whole family

Lightweight

Non-greasy

Non-oily

Pleasant feel

Fragrance free

No odor, no grease, no worries

Odorless

No odor

Adults no need to wash off when returning from outdoors

Tough on insects, gentle on skin

### Optional Label Claims (continued):

<u>Touch/Feel descriptors [to be used as stand-alone statements or inserted into additional statements as indicated below]</u>

Dry	Fresh	Not Greasy
Not Oily	Light	Non-Oily
Good	Comfortable	Pleasant
Greaseless	Not Sticky	Touchable
Non-Greasy	Not Wet	

Feels [insert touch/feel descriptor] (on) (on your skin)

[Insert touch/feel descriptor] feel (formula)

[Insert touch/feel descriptor] touch (formula)

[Insert touch/feel descriptor] formula

[Insert touch/feel descriptor] protection

[Insert touch/feel descriptor] skin feel

(Insect repellent that) leaves (your) skin feeling [insert touch/feel descriptor]

- (Light feel) (Light weight) (Strong) (Effective) (Proven) protection
- Feel good protection for (the entire family) (your family)
- Dry (shield) (defense) (performance) (repellent) (lotion)
- Smart (shield) (defense) (performance) (repellent) (lotion)
- (Formulated) (with) feel dry technology
- (Formulated) (with) dry feel technology
- Quick dry (ing)
- Fast dry (ing)
- Dries fast

### Industrial Use Optional Claims

Arc flash compliant

Will not affect flame resistant (FR) clothing

Insect Repellent formulated as an odorless body lotion with the active ingredient IR3535© to be used on exposed skin of outdoor [industrial] workers.

Non-flammable

Made by Americans for the Outdoor American Worker

Lineman's Glove Test Compliant

**ASTM F2621** 

ASTM D120

### Optional Label Claims (continued):

- Protection for the whole family
- Complete protection (from mosquitoes and ticks) for the entire family
- 8 hour protection for the entire family
- May repeat application when used as directed
- (clear), (colorless), (odorless)
- Relax and rely on [insert brand name] IR3535 protection from mosquito bites
- 8 hour protection
- · Repels mosquitoes which may carry Zika virus
- Repels ticks which may carry Lyme disease
- Safety Shield for your family
- Your personal bodyguard
- Your best friend for protection
- Protect yourself (and your loved ones)
- IR3535 is inspired from a naturally occurring amino acid
- May be left on overnight for adults [when used as directed]
- Instructions do not require washing skin after returning indoors for adults
- IR3535. Tough on [Mosquitoes] [Ticks]. Easy on you.
- IR3535. Protection On. [Mosquitoes] [Ticks] Off.
- IR3535. Guard On. [Mosquitoes] [Ticks] Off.
- IR3535. Guard On. [Mosquitoes] [Ticks] Repelled.
- IR3535. Protection On. [Mosquitoes] [Ticks] Repelled.
- Made to Guard Against Ticks and Mosquitoes
- Made to Protect Against Ticks and Mosquitoes

### Optional Label Claims/Graphics:

